REMARKS

The currently pending claims in this application are claims 16-21 with claim 16 and claim 21 being the only independent claims.

In the Office Action of March 22, 2005, the Examiner rejected claims 16-21 under 35 U.S.C. 103(a) as being unpatentable over Amplatz et al. U.S. Patent No. 4,995,866 in view of Gifford III, et al., U.S. Patent No. 5,695,504 and further view of Cohen, U.S. Patent No. 4,991,578. Applicants respectfully request that the application be reconsidered and allowed for the reasons explained below.

Claim 16 Would Not Be Obvious In View Of The Prior Art

Turning first to independent claim 16, it is respectfully submitted that the claimed combination of Amplatz et al., Gifford III, et al., and Cohen is not proper in the absence of applicants' disclosure.

In Amplatz et al., Figures 6A-6D (which are designated as "prior art" by Amplatz et al.) illustrate a combination needle and dilator apparatus being inserted into a blood vessel for the introduction of a catheter. The "prior art" includes a needle 60 with a cutting edge 61 and a sheath 62 which is carried about the needle 60 in a position which is proximately located to the cutting edge 61. The sheath 62 includes a forwardly facing shoulder 63 and has an inner diameter which is sized to receive

the needle 60. The needle 60 and sheath 62 are advanced into the lumen of the blood vessel 50.

In contrast to the claims of the present application, Amplatz et al. discloses that a distal end of the sheath 62 must not be embedded for engagement with the outer surface of the wall to provide for enlargement of the blood vessel 50. Instead, the distal end of the sheath 62 must be placed in the lumen of a blood vessel. As shown in Figures 6A-6D, the distal end of the sheath is inserted into the lumen of the blood vessel 50, and once so placed, engages the inner surface of the blood vessel so as to dilate the blood vessel and allow insertion and advancement of a guide wire 64 (see Figure 6D) in the blood vessel. Thus, Amplatz teaches engagement with the inner surface of the blood vessel rather than the claimed structure which is embedded into tissue for engagement with an outer surface of a tissue wall.

It must further be emphasized that the "prior art" device in Figures 6A-6B of Amplatz et al. discloses that at least a portion of the exterior surface of the lumen is compressed inwardly, in contrast to the claimed subject matter which provides for enlargement of an anatomic space. At column 5, lines 12-13, Amplatz et al. clearly acknowledges that the puncture of the lumen of the blood vessel by the "prior art" device causes the blood vessel 50 to "collapse locally," which is the opposite of the intended structure and function of the

invention set forth in claim 16. The lumen collapses further by any contact by the shoulder 63 of the sheath 62 against the outer surface of the blood vessel 50 (column 5, lines 13-15). Thus, Figures 6A-6D of Amplatz et al. teach away from the claimed subject matter.

In Figures 7A-7C, Amplatz' own alleged invention also teaches away from the claimed subject matter, and, as such, is no different from the "prior art" device in Figures 6A-6D. In Figures 7A-7C, Amplatz et al. allegedly overcomes the drawbacks in the prior art by sizing the needle 10 and sheath 20 to present a substantially smooth cylindrical surface so that the front portion 21 of the sheath does not engage the outer surface of the blood vessel 50. In this way, Amplatz' sheath 20 specifically teaches avoidance of any significant engagement with the outer surface. More particularly, Amplatz et al. teaches a structure which intentionally does not engage the outer surface to provide for enlargement of the anatomic space upon proximal movement of the access tube. Amplatz et al. instead expressly teaches that the device of Figures 7A-7D enters the lumen of the blood vessel 50 and engages the inner surface of the blood vessel 50 so as to allow insertion of the guide wire 64.

Accordingly, Amplatz et al. clearly lacks any teaching or suggestion for the claimed subject matter, and, in fact, provides an express teaching away from the claimed subject matter. In

view of such express teaching in Amplatz et al., it would not be obvious to combine Amplatz et al. with the other prior art references relied upon by the examiner, namely, Gifford III, et al. and Cohen.

The Alleged Combination Is Not Taught Or Suggested By the Prior Art In The Absence of Applicants' Disclosure

In the Office Action, it is presumed that it would be obvious to combine the apparatus in Amplatz et al. with the structures shown in Figs. 40A and 40D of Gifford III, et al., and in Figs. 3A and 3B of Cohen. However, applicants respectfully disagree as such combination would only be made using the hindsight provided by applicants' disclosure.

It must be emphasized that the apparatus in Figs. 6A-6D of Amplatz et al. expressly teaches an apparatus having a distal end which avoids engagement with the outer wall of the blood vessel and instead is inserted into the lumen of the blood vessel for engagement with the inner wall. Accordingly, Amplatz et al. expressly teaches an opposed structure which is clearly in contrast with the claimed subject matter.

Yet despite these express teachings by Amplatz, the office action presumes that it would be obvious to combine the apparatus of Amplatz et al. with the structures in Figs. 40A-40B of Gifford III, et al. and in Figs. 3A and 3B of Cohen with the reasoning that such combination is an "obvious design alternative."

However, such reasoning fails to reconcile the obvious express teaching in Amplatz against such combination. It is respectfully submitted that this alleged combination would only be made in view of the blueprint provided by applicants' disclosure. Otherwise, why would a person of ordinary skill in the relevant art be motivated to combine such references when Amplatz et al. expressly teaches against such combination? In the absence of applicants' disclosure, there is no motivation to combine such references.

Further, it is noted that other aspects of the references also discourage such combination. Gifford III, et al. discloses various vascular anastomosis devices which attach bypass grafts to a blocked blood vessel for the purpose of reestablishing blood flow to essential tissue areas which have been compromised by harmful conditions such as occlusions or stenosis. The structure and function of the device in Gifford III, et al. is clearly different from the structure and function of the apparatus in Amplatz et al. such that it would not be obvious to make the alleged combination.

In particular, the specific anastomosis device 496 relied upon in Figs. 40A-40D in Gifford III, et al. teaches that inner and outer graft rings 497 and 498 are placed around the distal end 259 of the graft vessel 254. Each graft ring 497, 498 includes corresponding staple members 499, 500 (see Figures 40A

and 40B). The staple members 499, 500 are driven by rotation through the end of a graft vessel wall 259 and into the side of a target vessel wall 255 (see Figure 40D) to attach the bypass graft.

It is respectfully submitted that the structure and function of the respective apparatuses in Amplatz et al. and Gifford III, et al. are significantly different so as to further discourage any such combination in the absence of applicants' disclosure. Where is the motivation to so combine these references based on such different structures and functions? In Gifford III, et al., the anastomosis device is designed and constructed to attach a bypass graft from a position disposed outside of the graft vessel so as to avoid contact with the interior of the graft vessel and provide a completely leak-free seal between the graft and the graft vessel. In Amplatz et al., the apparatus is design and constructed for puncturing and accessing a blood vessel lumen for insertion of a guide wire and such apparatus avoids engagement with the outer surface of the blood vessel at the puncture site.

In view of the above teachings, there is no motivation to combine the apparatus of Amplatz et al. with that of Gifford III, et al. in the absence of the hindsight provided by applicants' disclosure which is not a proper basis for an obviousness rejection.

Likewise, it would not be obvious to combine Cohen with the alleged combination of Amplatz et al. and Gifford III, et al. based on the differences in structure and function as taught by Cohen. In the Office Action, Figures 3A and 3B of Cohen are relied upon in combination with Amplatz et al. and Gifford III, et al. However, in addition to the reasons discussed above, such combination is further discouraged based on the different structure and function disclosed in Figure 3A and 3B of Cohen.

The structure in Figures 3A and 3B of Cohen is advanced intravenously (e.g., through the jugular or subclavian vein) to the heart and affixed to the interior of the right atrial wall 30 using a screw-type helical tip 40. The purpose of such structure in Cohen is for injection of a fluid 26 through the atrial heart wall 30 into the pericardium 14 so as to inflate the pericardium 14 (see Figure 2B). Cohen specifically teaches that the inflated pericardium 14 allows a lead 18 (see Figure 1) to be implanted via a sub-xiphoid location 20 into the narrow space between the pericardium 14 and the heart surface without puncturing the atrial wall 30 (or other heart surface) during lead implantation (column 8, lines 14-23; column 9, lines 12-23). Clearly, this structure and function of Cohen is different as compared to the disclosed structures and functions in Amplatz et al and Gifford III, et al., as described above, both of which are not concerned with lead implantation into the pericardium.

Accordingly, for all the above reasons, it would not be obvious to modify the apparatus of Amplatz et al. with the structure in Figures 40A-40B of Gifford III, et al. and the structure in Figures 3A and 3B of Cohen. Any combination of these references disregards the express teachings in Amplatz et al. against such combination in addition to other aspects which discourage such combination. As a result, any teaching or suggestion to modify these references is provided only by applicants' own disclosure which cannot be used as a blueprint to render the claimed subject matter obvious.

For these reasons, applicants respectfully submit that amended claim 16 would not be obvious. Claims 17-20 depend on independent claim 16 and would not be obvious, as they contain all the features of claim 16 which should be allowable for the reasons stated above.

Independent claim 21 was rejected for the same reasons as independent claim 16 and is respectfully believed to be allowable for similar reasons as discussed above.

For all of the above reasons, reconsideration and allowance are respectfully requested.

Respectfully submitted,

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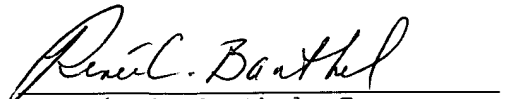
By: 

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